

Applicants find no teaching, suggestion or reference by Johansson et al of a method for treating insulin resistance in a patient with Metabolic Syndrome by decreasing insulin resistance. Johansson et al teach that growth hormone deficient patients are insulin resistant, while the present invention teaches the use of growth hormones to decrease insulin resistance associated with Metabolic Syndrome. In addition, the 1993 Fowelin et al study relied upon by Johansson et al teach the effects of the use of growth hormone on patients who are insulin sensitive and growth hormone deficient, while the present invention teaches the use of growth hormone to treat individuals who are insulin resistant due to the Metabolic Syndrome. Specifically, Fowelin et al teach that after 26 weeks of growth hormone treatment insulin sensitivity returns to base line value, while the present invention teaches that after 9 months of treatment with growth hormone in Metabolic Syndrome individuals there is a decrease in insulin resistance.

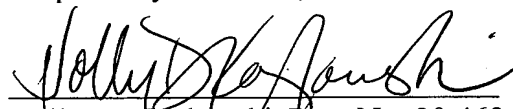
Anticipation under 35 U.S.C. §102(b) requires the disclosure in a single prior art reference of each element of the claims under consideration, *Alco Standard Corp. v. TVA*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). In view of the failure of Johansson et al to disclose a method for treating insulin resistance in a patient with the Metabolic Syndrome by decreasing insulin resistance, Johansson et al do not disclose each element of the present claims and therefore do not anticipate these claims under 35 U.S.C. §102.

Moreover, references relied upon to support a rejection under 35 U.S.C. §103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public, *In re Payne*, 203 U.S.P.Q. 245 (CCPA 1979). In view of the failure of Johansson et al to teach, suggest or recognize a method for treating insulin resistance in a patient with the Metabolic Syndrome by decreasing insulin resistance, the reference does not provide an enabling disclosure of the present invention, and therefore does not support a rejection of the claims under 35 U.S.C. §103.

It is therefore submitted that the compositions defined by claims 22-24 are neither anticipated by nor rendered obvious over Johansson et al and are patentably distinguishable therefrom, whereby the rejections under 35 U.S.C. §§102 and 103 have been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the Examiner's rejections under 35 U.S.C. §§ 102 and 103, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



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Version With Markings Showing Changes Made

Please amend the paragraph at page 1, lines 4-10 to read as follows:

The present invention relates to the use of growth hormone, preferably human growth hormone or analogues thereof for the manufacturing of a medicament for treatment of individuals with [the] Metabolic [syndrome] Syndrome (also labeled Syndrome X). They include individuals with abdominal/visceral obesity and its metabolic and circulatory consequences including insulin resistance, lipoprotein aberrations and hypertension. The medicament is also used to increase insulin sensitivity and for treatment and prevention of non-insulin dependent diabetes mellitus.

Please amend claims 22 and 41 to read as follows:

22. (Fourth Amendment) A method for treating a patient for insulin resistance to decrease the insulin resistance, said patient having [the] Metabolic Syndrome [, wherein said syndrome comprises] comprising Primary Insulin Resistance and abdominal/visceral obesity, wherein said method comprises administering to said patient [in] growth hormone or a functional derivative thereof in [the] an amount effective for decreasing insulin resistance of said patient.

41. (Amended) A method according to claim 22 [of increasing insulin sensitivity of a patient having the Metabolic Syndrome], wherein said method [comprising] comprises administering recombinant human growth hormone at about 9.5 µg/kg daily.



A DOCPHOENIX

APPL PARTS

IMIS
Internal Misc. Paper
01-23-02 LET. 81
Misc. Incoming Letter

371P
PCT Papers in a 371 Application

A...
Amendment Including Elections

ABST
Abstract

ADS
Application Data Sheet

AF/D
Affidavit or Exhibit Received

APPENDIX
Appendix

ARTIFACT
Artifact

BIB
Bib Data Sheet

CLM
Claim

COMPUTER
Computer Program Listing

CRFL
All CRF Papers for Backfile

DIST
Terminal Disclaimer Filed

DRW
Drawings

FOR
Foreign Reference

FRPR
Foreign Priority Papers

IDS
IDS Including 1449

NPL
Non-Patent Literature

OATH
Oath or Declaration

PET.
Petition

RETMAIL
Mail Returned by USPS

SEQLIST
Sequence Listing

SPEC
Specification

SPEC NO
Specification Not in English

TRNA
Transmittal New Application

CTNF
Count Non-Final

CTRS
Count Restriction

EXIN
Examiner Interview

M903
DO/EO Acceptance

M905
DO/EO Missing Requirement

NFDR
Formal Drawing Required

NOA
Notice of Allowance

PETDEC
Petition Decision

OUTGOING

CTMS
Misc. Office Action

1449
Signed 1449

892
892

ABN
Abandonment

APDEC
Board of Appeals Decision

APEA
Examiner Answer

CTAV
Count Advisory Action

CTEQ
Count Ex parte Quayle

CTFR
Count Final Rejection

INCOMING

AP.B
Appeal Brief

C.AD
Change of Address

N/AP
Notice of Appeal

PA..
Change in Power of Attorney

REM
Applicant Remarks in Amendment

XT/
Extension of Time filed separate

BACKFILE DOCUMENT INDEX SHEET

Internal

SRNT
Examiner Search Notes

CLMPTO
PTO Prepared Complete Claim Set

ECBOX
Evidence Copy Box Identification

WCLM
Claim Worksheet

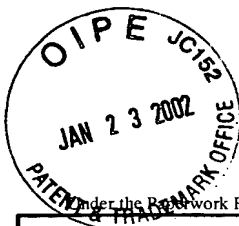
WFEE
Fee Worksheet

File Wrapper

FWCLM
File Wrapper Claim

IIFW
File Wrapper Issue Information

SRFW
File Wrapper Search Info



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REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

Subsection (b) of 35 U.S.C. §132, effective on May 29, 2000,
provides for continued examination of a utility or plant application
filed on or after June 8, 1995.
See The American Inventors Protection Act of 1999 (AIPA).

Application Number	09/80,366
Filing Date	March 31, 1998
First Named Inventor	Gudmundur Johansson et al
Group Art Unit	1653
Examiner Name	F. Moezie
Attorney Docket Number	10806-181

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application.
NOTE: 37 C.F.R. § 1.114 is effective on May 29, 2000. If the above-identified application was filed prior to May 29, 2000, applicant may wish to consider filing a continued prosecution application (CPA) under 37 C.F.R. § 1.53 (d) (PTO/SB/29) instead of a RCE to be eligible for the patent term adjustment provisions of the AIPA. See Changes to Application Examination and Provisional Application Practice, Interim Rule, 65 Fed. Reg. 14865 (Mar. 20, 2000), 1233 Off. Gaz. Pat. Office 47 (Apr. 11, 2000), which established RCE practice.

1. Submission required under 37 C.F.R. §1.114

- a. ☐ Previously submitted
- i. ☐ Consider the amendment(s)/reply under 37 C.F.R. §1.116 previously filed on _____
(Any unentered amendment(s) referred to above will be entered.)
- ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- iii. ☐ Other _____
- b. ☒ Enclosed
- i. ☒ Amendment/Reply
- ii. ☐ Affidavit(s)/Declaration(s)
- iii. ☐ Information Disclosure Statement (IDS)
- iv. ☒ Two Month Extension
- v. ☒ Appointment of Associate Attorneys and Change of Correspondence Address

2. Miscellaneous

- a. ☐ Suspension of action on the above-identified application is requested under 37 C.F.R. §1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. §1.17(i) required.)
- b. ☐ Other _____

3. Fees The RCE fee under 37 C.F.R. §1.17(e) is required by 37 C.F.R. §1.114 when the RCE is filed.

- a. ☐ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. _____
- i. ☐ RCE fee required under 37 C.F.R. §1.17(e)
- ii. ☐ Extension of time fee (37 C.F.R. §§ 1.136 and 1.17)
- iii. ☐ Other _____
- b. ☒ Check in the amount of \$ 1140.00 enclosed
- c. ☒ The Director is hereby authorized to charge any deficiencies, or credit any overpayments, to Deposit Account No. 04-1133

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT REQUIRED

Name (Type/Print)	Holly D. Kozlowski	Registration No. (Attorney/Agent)	30,468
Signature		Date	November 19, 2001

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Box RCE, Washington, DC 20231, or facsimile transmitted to the U.S. Patent and Trademark Office on the below date.

Name (Type/Print)	Holly D. Kozlowski	Date	November 19, 2001
Signature		Date	November 19, 2001

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND Fees and Completed Forms to the following address: Commissioner for Patents, Box RCE, Washington, DC 20231.